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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,728	12/05/2003	George F. Kick	ONSET.002A	1724

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EXAMINER

SIMPSON, SARAH A

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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03/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,728	Applicant(s) KICK ET AL.	
	Examiner SARAH A. SIMPSON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/19/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the amendment filed 11/19/2009, amending claims 25, 27, 47, 49, 60, 62, 72, 74, 87 and 88, and canceling claims 1-24, 26, 29-46, 48, 51-59, 61, 64-71, 73, 76-82 and 90. Accordingly, claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 are currently pending and presented for examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 25, 47, 60, 72 and 87 have been amended to recite, "the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on the one side of the distal region". The preceding constitutes as new matter. It is not until application no. 10/884017, a

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continuation in part of the current application, is filed that the direction and position of the creases are disclosed in the specification in paragraph [0060] and Figures 3A-C.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 27-28, 60, 62-63 and 83-89 rejected under 35 U.S.C. 103(a) as obvious over **Nishtala et al. (US 2001/0012950 A1)** in view of **Fuqua (US 4,738,666)** and further in view of **Fourkas et al. (US 6,808,520 B1)**.

Regarding claims 25, 27-28, 60, 62-63 and 83-89, Nishtala discloses a method of providing percutaneous access, said method comprising: making an incision through skin; inserting a guidewire through the incision in the skin and into or through the renal collection system, percutaneously inserting an elongate tubular structure through the incision in the skin and over the guidewire and into the renal collection system, the

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elongate tubular structure comprising a distal region, a proximal region, and a tapered region all of which may be folded ([0096]; figs. 1B-D). Nishtala teaches various tubular embodiments that may be expanded by any active or passive dilating elements such as by inflating a balloon ([0081], [0086], [0098]) that is positioned within an interior lumen of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile. Nishtala also teaches the balloon may be removed from said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end ([0173]).

Nishtala fails to disclose wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and longitudinal creases, the proximal region having a second, greater cross-sectional profile, the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular

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jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]).

Fuqua teaches a method of providing percutaneous access, said method comprising: percutaneously inserting into or through the renal collection system (column 4, lines 24-26), an elongate tubular structure (14) having a first, folded, substantially continuous, smaller cross-sectional profile into the renal collection system, the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region (fig. 3); expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 5, 6); and inflating a balloon (38) that is positioned within an interior lumen of the folded distal region of the elongate tubular structure to radially expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile (column 5, lines 63-64); and releasing the elongate tubular structure from a constraining tubular jacket (60), the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation (figs. 5-6) and separating the jacket from the elongate tubular structure (figs. 7-8).

Forukas teaches a circumferentially continuous tapered tubular dilator and sheath wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile (figs. 22, 23).

Given the teachings of Fuqua and Forukas, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Nistala wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]). The tapered region of the folded tubular member provides for a safer, faster, and easier placement of the tube as well reducing trauma by allowing the narrow initial penetration of the tube to be expanded to a size capable of receiving other surgical instruments, as disclosed by Forukas. The constraining tubular jacket provides advantageous delivery methods, as the jacket prevents the tube from premature expansion.

5. **Claims 47, 49-50, 72 and 74-75** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nishtala et al. (US 2001/0012950 A1)** in view of **Fuqua (US**

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4,738,666) and **Forukas et al. (US 6,808,520 B1)** and further in view of **Bacich et al. (US 5,810,776)**.

Regarding claims 47, 49-50, 72 and 74-75, Nishtala discloses a method of providing percutaneous access, said method comprising: making an incision through skin; inserting a guidewire through the incision in the skin and into or through the renal collection system, percutaneously inserting an elongate tubular structure through the incision in the skin and over the guidewire and into the renal collection system, the elongate tubular structure comprising a distal region, a proximal region, and a tapered region all of which may be folded ([0096]; figs. 1B-D). Nishtala teaches various tubular embodiments that may be expanded by any active or passive dilating elements such as by inflating a balloon ([0081], [0086], [0098]) that is positioned within an interior lumen of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile. Nishtala also teaches the balloon may be removed from said distal region of said elongate tubular structure to open the interior lumen in said elongate tubular structure, the interior lumen open to an external environment outside the skin on its proximal end and open to the renal collection system on its distal end ([0173]).

Nishtala fails to disclose wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile, the longitudinal creases of the distal region comprising two creased

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outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]).

Fuqua teaches a method of providing percutaneous access, said method comprising: percutaneously inserting into or through the renal collection system (column 4, lines 24-26), an elongate tubular structure (14) having a first, folded, substantially continuous, smaller cross-sectional profile into the renal collection system, the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region (fig. 3); expanding said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to a second, greater cross-sectional profile (figs. 5, 6); and inflating a balloon (38) that is positioned within an interior lumen of the folded distal region of the elongate tubular structure to radially expand said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-

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sectional profile (column 5, lines 63-64); and releasing the elongate tubular structure from a constraining tubular jacket (60), the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation (figs. 5-6) and separating the jacket from the elongate tubular structure (figs. 7-8).

Forukas teaches a circumferentially continuous tapered tubular dilator and sheath wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile (figs. 22, 23).

Given the teachings of Fuqua and Forukas, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Nistala wherein the tapered region of the tubular structure is between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and the proximal region having a second, greater cross-sectional profile; and releasing the elongate tubular structure from a constraining tubular jacket, the constraining tubular jacket sharing the same longitudinal axis as the elongate tubular structure, wherein releasing the elongate tubular structure from the constraining tubular jacket comprises tearing said tubular jacket along a perforation. However, Nishtala teaches that all of the dilating elements may be used with a membrane or protective oversheath ([0082]). The tapered region of the folded tubular member provides for a safer, faster, and easier

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placement of the tube as well reducing trauma by allowing the narrow initial penetration of the tube to be expanded to a size capable of receiving other surgical instruments, as disclosed by Forukas. The constraining tubular jacket provides advantageous delivery methods, as the jacket prevents the tube from premature expansion.

Nistala fails to disclose wherein the elongate tubular body has a beveled distal tip.

However, Bacich et al. teach an expandable elongate tubular body (120) which as a beveled distal tip (fig. 1) comprising a leading edge and a trailing edge, wherein the at least one longitudinal creased section is positioned on the perimeter of the elongate tubular body generally opposite the side of the elongate tubular body on which the leading edge is positioned (figs. 1-4).

Given the teachings of Bacich et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method with a beveled distal tip. The beveled distal tip would provide a smooth and efficient introduction of the expandable sheath into the body.

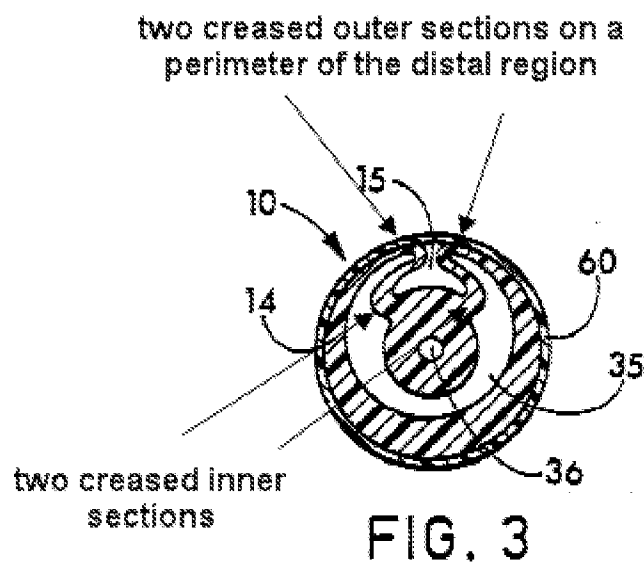
Response to Arguments

Applicant's arguments with respect to claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed with respect to Fuqua have been fully considered but they are not persuasive. As reproduced below, Fuqua discloses the longitudinal creases

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of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on the one side of the distal region and inflating a balloon (36) that is positioned within an interior lumen (35) of the folded distal region of the tubular structure (fig. 3).



Although the balloon is not separate from the wall of the tube, when in the contracted position as shown above, the balloon is positioned within an interior lumen of the folded section.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731
3/12/2010

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/15/10